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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,060

03/15/2005

Wilhelm Scherze

1998.003US1

9011

21186

7590

12/26/2008

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EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

12/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,060	Applicant(s) SCHERZE ET AL.	
	Examiner AMANDA P. WOOD	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 December 2008 has been entered.

Claims 1-15 are pending and have been examined on the merits.

Applicant's arguments with respect to the rejection under USC 103(a) of claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Withdrawn Rejections

Based upon the newly submitted amendments to the claims, the 112, 2nd paragraph rejection dated 10 January 2008 has been withdrawn.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kearney, as cited previously, in view of Delucas et al (US 6,447,726) in further view of Pfaller, as cited previously.

Kearney teaches a method for culturing and testing of cells and tissues in a fully controlled thermal and gaseous environment, using an automated system (i.e., cell culture system) which provides a precision metering system for the introduction of controlled volumes of media as well as in-line detectors and monitoring devices allowing continuous assessment of the viability and metabolic state of each cell without the need for invasive procedures. Furthermore, Kearney teaches that the system includes a computer control allowing adjustment of rates of oxygenation, nutrient feed, and operation of heat control. Kearney also teaches that the system has a temperature sensor within each bioreactor (i.e., cell culture chamber) in the system which senses the temperature and conveys this information to the onboard computer control to provide accurate temperature control. In addition, Kearney teaches that appropriate sensors are provided within the gas pathway to sense dissolved oxygen and/or acidity (see, for

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example, col. 6, lines 10-25). Kearney further teaches that a computer-controlled fluid pathway provides a supply of media, nutrients and chemical agents to the cells of the bioreactors, allowing control of administration of fluids as well as removal thereof. The bioreactors can be connected either in series or in parallel, according to Kearney (see, for example, col. 5, lines 55-67, col. 6, lines 1-10, col. 20, lines 30-50). Furthermore, Kearney teach that gases are continuously passed from bioreactor to bioreactor via a series of serially disposed T-unions (see, for example, col. 14, lines 45-67). In addition, Kearney teaches that the invention can include an automated microscope/CCD camera system to allow direct microscopic analysis of living cells during the study (see, for example, col. 20, lines 15-35). Kearney further teaches that determining the biotransformation of test materials can be accomplished by connecting two bioreactors in series, wherein the first bioreactor contains a target tissue and the second bioreactor contains hepatic tissue, and effluent from the second bioreactor may be removed for analytical testing, or cells may be observed directly (see, for example, col. 20, lines 30-67).

Kearney does not expressly teach a method wherein the cell culture is continuously microscopically observed by utilizing a camera which is disposed on a displaceable table for movement of the camera with respect to the cell culture chamber.

Delucas et al beneficially teach a system and method for protein crystal growth which comprises a chassis housing a video camera monitoring and translation mechanism within the protein crystal growth system. Delucas et al teach that the system further comprises protein crystal growth tray assemblies which are monitored by

the video monitoring system, and that a translation mechanism arranged on the chassis and coupled to the video camera allows the video camera to be positioned above the protein crystal growth assembly. In addition, Delucas et al beneficially teach that the system includes a controller which provides control signals to the translation mechanism for controlling the translation and positioning of the video camera (see, for example, col. 1, lines 25-65, col. 2, lines 9-55, and figures 14-24).

Kearney and Delucas et al do not expressly teach a method wherein one cell culture, each of a different type, is established on both sides of a gas-permeable membrane inside at least one cell culture chamber for the purpose of a direct co-cultivation of both cell cultures.

Pfaller beneficially teaches a cell culture support and method for co-culturing cells wherein the inflow and outflow channels are designed to provide homogenous replacement of medium, thereby offering the possibility to perfuse nutrients of different composition at the top (apical) and bottom (basal or basolateral) side of the cell culture growth support. Pfaller further beneficially teaches that the cell culture growth support is bounded by a gas permeable membrane on both sides, and therefore, Pfaller teaches a method wherein different cell types are cultured on both sides of a gas permeable membrane in a cell culture chamber for direct co-cultivation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method and system of culturing cells disclosed by Kearney based upon the beneficial teachings provided by Delucas et al, with respect to providing a camera which can be positioned for continuous observation

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of biological experiments within an environmentally-controlled chamber, and by Pfaller, with respect to the art-recognized method of co-culturing cells by providing two different nutrient compositions to apical and basolateral cells, as discussed above. Kearney specifically teaches that his automated cell culturing system can be used for co-culturing cells, and that co-cultures of rat myocytes and neuronal tissue have been grown and tested using the system. Delucas et al particularly teach that a camera system capable of being positioned with respect to an environmentally-controlled chamber for housing biological experiments is useful for providing real-time images of the experiments for the purpose of allowing such experiments to be carried out in limited space. Additionally, Kearney teaches that sensors for pH and oxygen are provided in the cell culture chambers known in the art, and that the cell culture chambers can be used to test and culture cells and tissues, and therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to measure cell culture parameters relevant to such cultures for the purpose of conducting the tests. Pfaller specifically teaches a method and apparatus that has an advantage over other cell culture systems in that it provides means for continuous replacement of culture medium while allowing for defined partial pressures of gases in immediate contact with the culture medium due to the use of a membrane impermeable to liquids but permeable to gases. Furthermore, Pfaller teaches that such a system allows for the perfusion of different medium to the apical and basolateral sides of the cell culture support, thereby providing organotypic culture conditions. Therefore, it would have been both obvious and beneficial for one of ordinary skill in the art to modify the

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methods and systems provided by Kearney using the methods of Pfaller, so as to provide a method for direct co-culture of cells while still providing a self-contained environment free from contamination, for the expected benefit of culturing cells under conditions similar to that found in vivo.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

/Ralph Gitomer/
Primary Examiner, Art Unit 1657